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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/602,833	06/23/00	TURNER A	8535-036-999

020583
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1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

HM22/0705

EXAMINER	
DHRUVA, B	
ART UNIT	**PAPER NUMBER**
1632	5

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/602,833	TURNER ET AL.	
	Examiner	Art Unit	
	Bharati R. Dhruva	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

A complete response to this action must include a response to the restriction and the sequence compliance.

Notice of Noncompliance with Sequence Rules

This application contains sequence disclosure that are encompassed by the definition for nucleotide and /or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29,May 15,1990 and at 55 FR 18230, May 1,1990. If the effective date of filing is on or after July 1,1998, see the final rulemaking notice published at 63 FR 29620 (June 1,1998) and 1211 OG 82 (June 23,1998).

This application does not contain, as a separate part of the disclosure on paper copy, a 'Sequence Listing" as required by 37 C.F.R. 1.821(c) and also sequence listing in computer readable form is submitted as required by 37 C.F.R. 1.821(e).

Applicant must provide an initial computer readable form (CRF) copy and an initial paper copy of the "Sequence Listing" together with a statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. 37 C.F.R. 1.821(e) or 37 C.F.R. 1.821(f) or 37 C.F.R. 1.821(g) or 37 C.F.R. 1.821(b) or 37 C.F.R. 1.821(d).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, and 8, drawn to nucleic acid classified in class 536 subclass 23.1.

II. Claim 7, drawn to a transgenic animal classified in class 800 subclass 3.

III. Claims 9-13 drawn to proteins classified in class 530 subclass 300^{+}.

IV. Claim 14 drawn to antibody classified in class 424 subclass 130.1.

V. Claim 15 drawn to method of drug discovery using protein classified in class 435 subclass 7.1.

VI. Claim 16 drawn to a method of screening for compound using protein classified in class 435 subclass 7.1.

VII. Claim 17 drawn to a method of identifying a compound, which modulates expression-using cell, classified in class 435 subclass 4.

VIII. Claim18-19 drawn to a method of transferring nucleic acid in a cell classified in class 435 subclass 455.

IX. Claim 20 drawn to a method of treating disease by administering a compound that modulates the activity or expression of a protein is not classifiable.

(***a***) On selection of **Group I or Group VII or Group IX,** Applicants are advised to **elect one** of the following sequences; SEQ ID: 1 and 3.

(*b*) On selection of **Group III,** Applicants are advised to **elect one** of the following sequences from SEQ ID: 2 and 4.

Inventions of Group I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. In the instant case the group I invention nucleic acid can be used as a hybridization probe or for production of protein while group II invention transgenic animal can be used as a model for human disease or testing therapeutic agents.

Inventions of groups III and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group I have separate and distinct chemical entity than the group III proteins. Furthermore, the group I invention nucleic acid can be used as a hybridization probe or for production of protein and group III can be used for production of antibody or as a therapeutic agent.

Inventions of groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different uses and mode of operation. The group I invention nucleic acid can be used as a hybridization probe or

for production of protein while group IV invention antibody can be used for diagnostic or as a therapeutic agent.

Inventions of groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Group II invention transgenic animal can be used as a model for human disease or as a therapeutic agents while group III invention be used for production of antibody or as a diagnostic agent.

Inventions groups II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Group II invention transgenic animal can be used as a model for human disease or as a therapeutic agents while group IV invention antibody can be used in diagnostic assay.

Inventions of group III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different physiochemical structure and functions. Thought the protein and antibody are related due to necessary steric complementarity of the two they are distinct inventions because the protein can be used in materially different process from the production of antibody such as in a

pharmaceutical composition or as an agent for ligand assay. Furthermore the protein and antibody have different amino acid compositions. Therefore the invention are distinct.

Inventions of groups I-IV and Groups V- XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups V-XI are different methods; a method of drug discovery, method of screening for a compound, method of transferring a cell using nucleic acid, and a method of identifying a compound using cell transformed with nucleic acid. They differ with respect to ingredients, method steps and endpoint: therefore each method is patentably separate.

The inventions are distinct, each from the other because of the following reasons:

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Bharati R. Dhruva whose telephone number is (703) - 605-1157. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703) 308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and for After Final communications.

Question of formal matters can be directed to the patent analyst Phillips Williams, whose phone number is (703) 305-3482.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0196.

BRD

June 19, 2001

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER